



Planning, Scoping, and Problem Formulation for Cumulative Risk Analysis

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Risk Assessment Paradigm Guides EPA Rules and Research

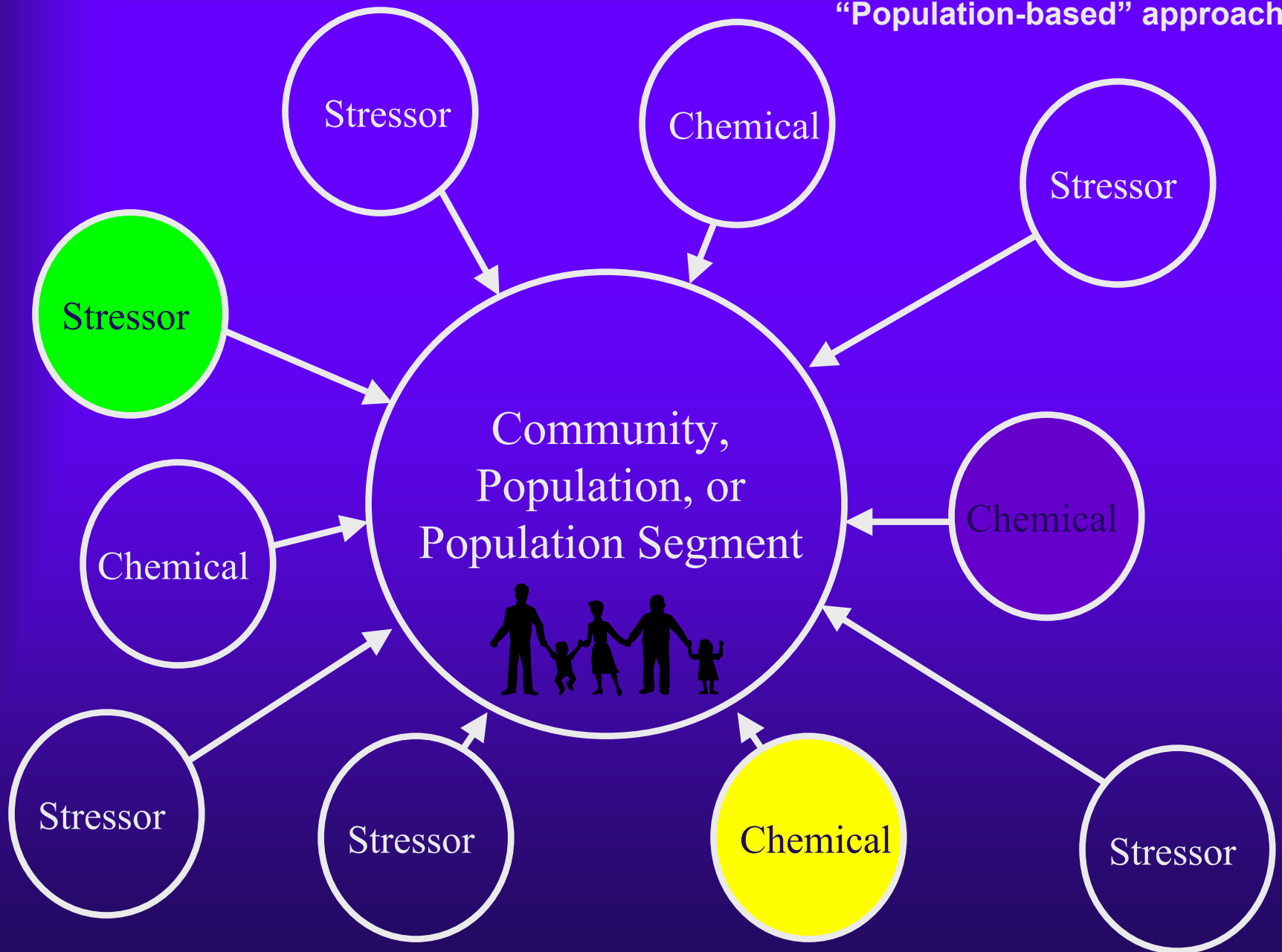
- ◆ NRC (1983) defined risk paradigm
- ◆ EPA developed first cancer guideline 1986.
- ◆ EPA reorganized ORD around risk assessment paradigm.
- ◆ Risk assessments have proliferated for rules and regulatory decisions.

Estimating Risks is becoming more complex

- ◆ NRC (1994 and 1996) described risk management/assessment and stakeholder interaction.
- ◆ Presidential/Congressional Commission (1997) stresses deliberation to involve stakeholders throughout process.
- ◆ Environmental Justice issues expand concerns for communities and cumulative risks beyond chemicals.




“Population-based” approach



Framework Definition

- ◆ **Cumulative risk assessment:** An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors.

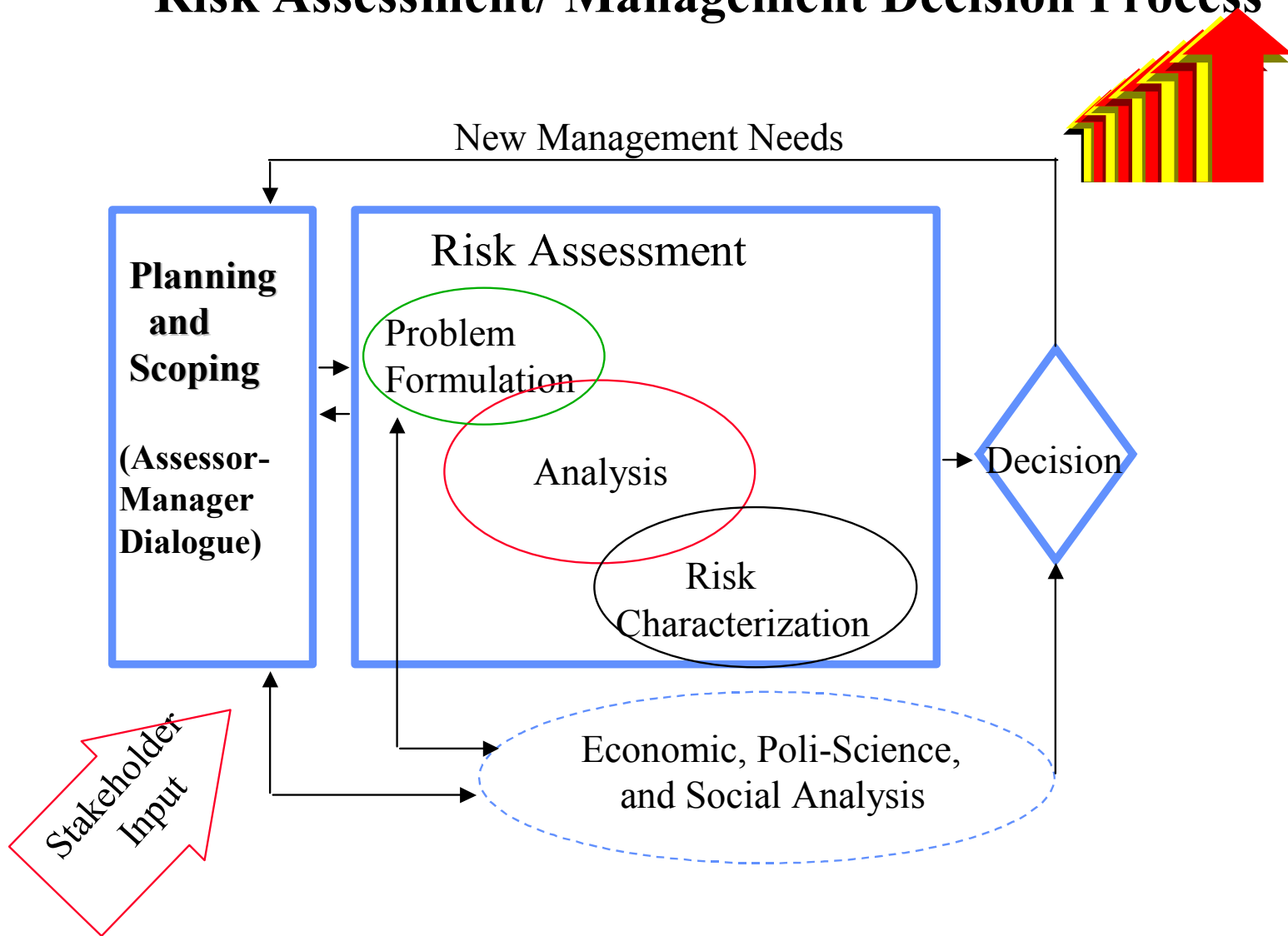
Source: Draft CR Framework



Planning & Scoping and Problem Formulation should be done

- ◆ These steps clarify the purpose for the assessment and stakeholder input, make the decision rationale transparent, and promote consistent and reasonable outcomes.
- ◆ Consistent with learned advice and agency practitioner experience.
- ◆ To consider risks and impacts and how they may interact over time and space.

Risk Assessment/ Management Decision Process





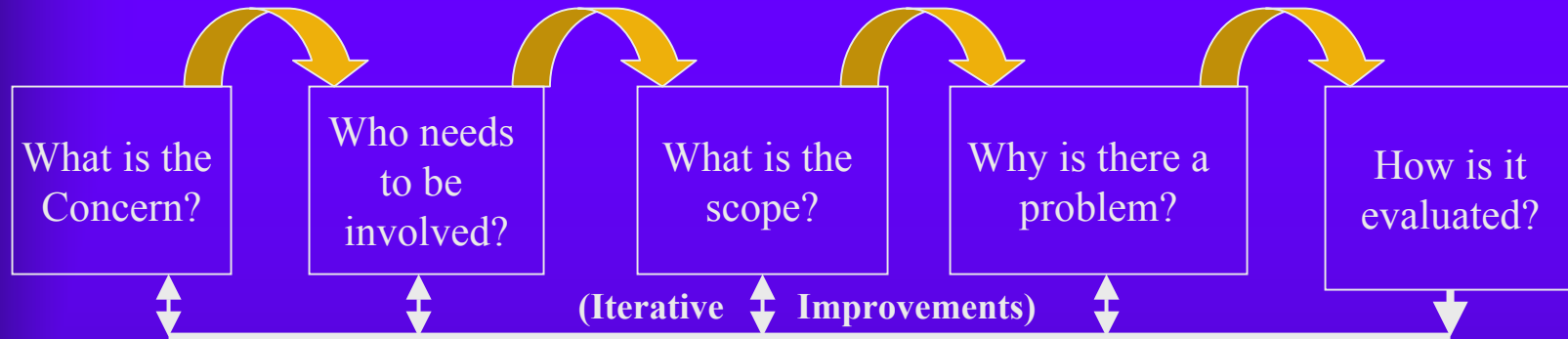
Key Steps Before the Assessment

- ◆ Determine overall purpose, risk management objectives, and analysis needs.
- ◆ Define the problem, its scope, resources, and who needs to be involved.
- ◆ What will be included and what will not?
- ◆ Develop a conceptual model and analysis plan for the assessment.



Planning and Scoping Steps

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- * Begin dialogue on nature of concern and analysis to inform risk management decisions

- * Identify participants (technical, affected and interested parties).

- * Decide what will and will not be included.

- * Develop a conceptual model of potential cause and effects.

- * An analysis plan....



What is the Concern?



Planning Dialogue

Risk Assessor

1. Background Knowledge
 - a. scale of the risk
 - b. critical endpoints
2. Available/appropriate data (where?)
3. Sources, stressors, effects
4. Gaps
5. Potential RM options



Risk Manager

1. Why is RA needed?
2. Risk Management goals
3. Policy concerns
4. Political concerns
5. Timing/Resources
6. Acceptable Levels of uncertainty?
7. Potential RM options

Stakeholders

1. Values
2. Impacts

Economists

1. Benefits
2. Tradeoffs
3. RM option costs



Problem Formulation



Scoping Questions

What are the relevant sources of stress?

What are the stressors of concern?

What are the relevant paths and routes of exposure?

Who and what are at risk?

What are the health assessment endpoints and ecological assessment endpoints?

What questions do the parties want the assessment to answer?



Public Involvement Functions

- ◆ Identify interested and affected public
- ◆ Provide information/advice
- ◆ Receive input on public's concerns, exposures, effects
- ◆ Assimilate input and provide feedback on the problem and solutions

Exposure and Stakeholders

How often do they eat fish?
What part of the fish do they
Eat?
Do they drink water from
the sites of concern? ...



Health status of stakeholders

- Pre-existing disease?
- Other exposures?
- Dietary habits?
- Lifestyle?
- Health care? ...

Concerns of stakeholders

- other unidentified contaminants?
- safety of wild food supply?
- costs of risk management?
- affects on life style, beliefs, etc.
- scientific uncertainty?



Conceptual Model

- ◆ Shows relationships between assessment endpoints and stressors.
- ◆ Reflects both scientific hypothesis and a rationale for accumulating risks from stressors affecting common receptors.
- ◆ Shows explicit hypothetical cause and effect linkages.





Conceptual Model Development

- 1. Define the goals and assessment context**
- 2. Delineate scales and boundaries**
- 3. Inventory land uses/activities**
- 4. Describe the potential stresses and sources**
- 5. Identify contaminant release mechanisms**



Conceptual Model Development (cont.)

- 6. Describe exposure pathways**
- 7. Identify stressor - receptor co-occurrences**
- 8. Identify health/ecological endpoints**
- 9. Determine specific health/ecological measures**
- 10. Develop a suite of risk hypotheses**
- 11. Rank relative importance of potential risks**

General Conceptual Model Format

Societal Drivers
(Landscape Activities)



System Stress



Stress Regime/Exposure Pathways



**Disturbance/Stressor Co-occurrences
with Receptors**



Primary/Secondary Effects
(Proposed Causal Linkages)



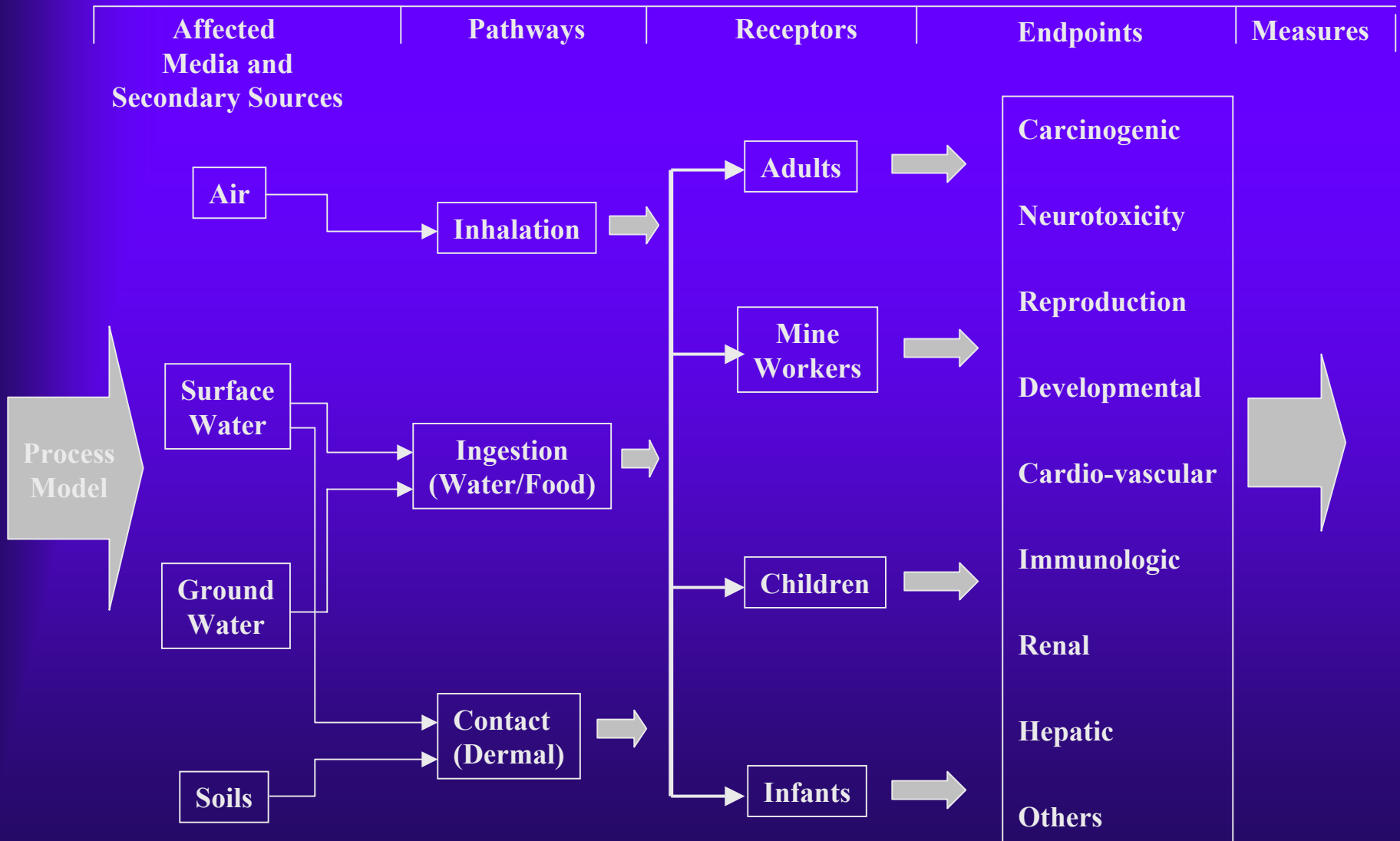
Health/Ecological Endpoints



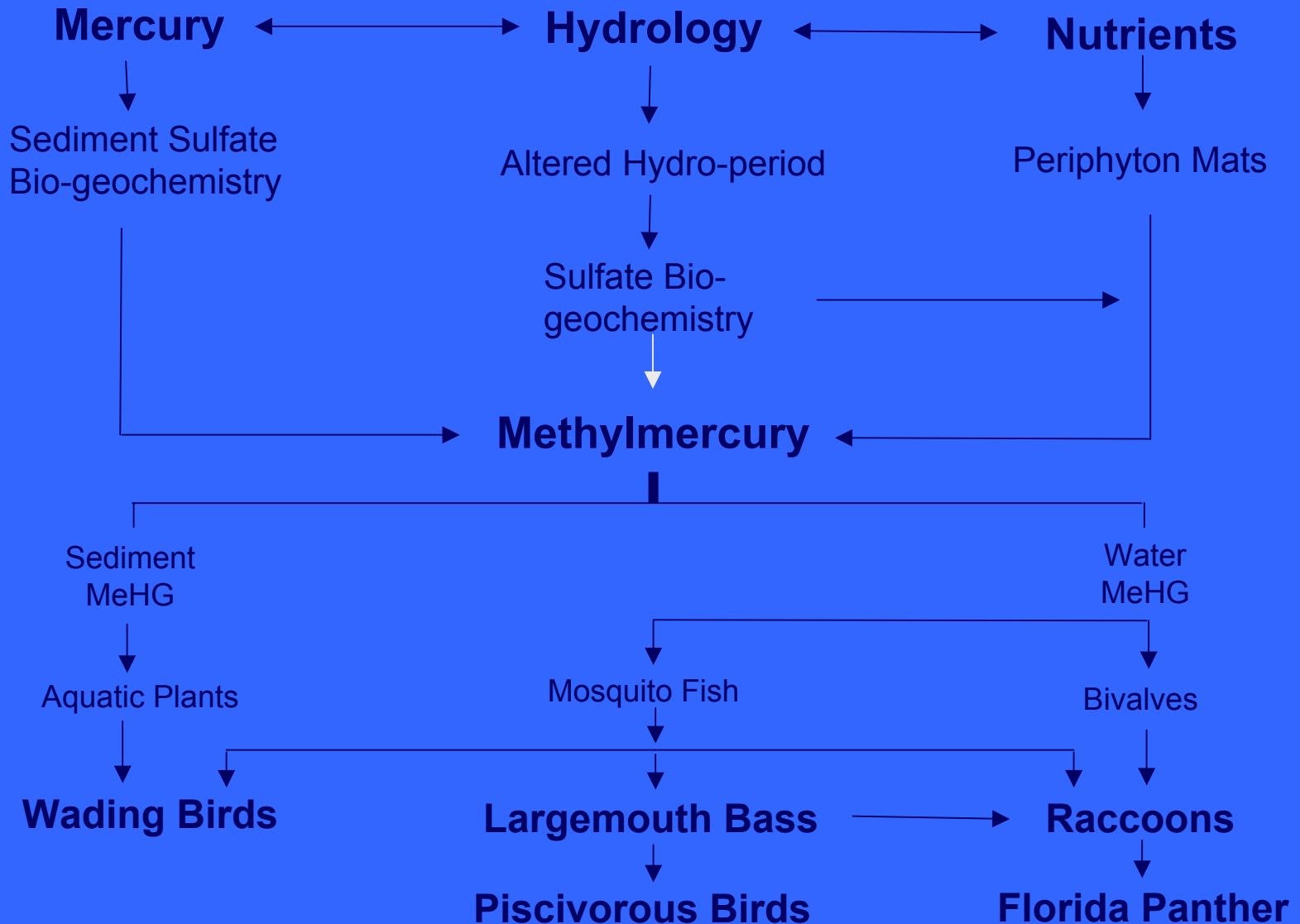
Measurements



Human Health Effects Conceptual Model



Hydrology, Mercury, and Nutrient Interactions





Analysis Plan for the Assessment

- ◆ Describes agreements on data sources, models, data quality, and methods for the risk assessment or other analysis.
- ◆ Carries forward assumptions, rationale for scope, stakeholder values and risk management objectives.
- ◆ Helps the assessment inform risk management option selection.





Analysis Plan Lessons

- ◆ Focus on a Risk Decision Product helps set data needs, approach, and public input.
- ◆ The analysis plan clarifies resource issues and options to collect information.
- ◆ Analysis planning improves risk characterization and saves resources.



Stressor-Stressor Interaction Ranking

(After Harris et al. 1994)

Stressor 1 ↓	Impacted Stressors (Stressor 2)							
	Scour	Susp. Particles	Sediments	Nutrients	BOD	Metals	Diazinon	Carp
Scour	—	2 ⁺	3 ⁻	1 ⁺	1 ⁺	1 ⁺	1 ⁺	1 ⁻
Susp. Particles	0	—	3 ⁺	1 ⁺	2 ⁺	1 ⁺	1 ⁺	1 ⁺
Sediments	0	2 ⁻	—	1 ⁺	1 ⁺	1 ⁺	0	1 ⁺
Nutrients	0	2 ⁺	1 ⁺	—	2 ⁺	1 ⁻	0	1 ⁺
BOD	0	1 ⁺	2 ⁺	1 ⁺	—	0	0	1 ⁺
Metals	0	0	0	0	0	—	0	1 ⁻
Diazinon	0	0	0	0	0	0	—	1 ⁻
Carp	0	1 ⁺	0	1 ⁺	0	0	0	—


+ exacerbating; - diminishing; 0 no impact; 1 small impact; 2 moderate impact; 3 large impact

Impact Matrix for Green Bay Assessment

(After Harris et al. 1994)

Stressors	Impact Criteria					
	Human Health	Aesthetic	Biota	Energy/ Nutrients	Economics	Synergy
Nutrient Loading(NL)	0	3	3	3	2	2
Heavy Metals (HM)	1	0	1	1	1	1
Wetland/Shoreline Fill	0	2	3	2	1	1
Solids Loading (SL)	0	3	3	3	2	2
Persistent Organics (PO)	2	0	1	1	2	1
BOD	0	1	2	1	3	2
Exotic invasions(EI)	0	1	3	2	2	1
Non-persistent toxics	0	0	1	1	2	1

Impact scale: 0, no apparent impact; 1, minor impact; 2, moderate impact; 3, major impact



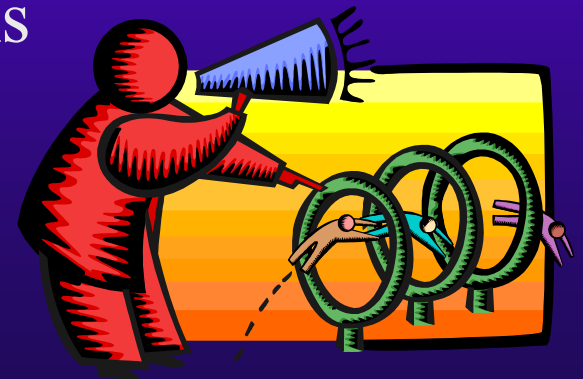
Desirable Outcomes from Planning and Scoping

- ◆ Assessment questions are clear and accepted by all parties.
- ◆ Stakeholders understand what assessment could show and the RM decision rationale.
- ◆ RM decision consequences are evaluated.
- ◆ Risks/Impacts are managed or avoided more effectively and efficiently.



Lessons from Case Studies

- ◆ Current cases show what we can do and some of what we need
- ◆ In the future, we must apply guidance and the framework prospectively to:
 - recognize critical aspects of environmental problems for each specific analysis
 - evaluate stressor interactions
 - engage key stakeholders





Additional Information

- ◆ <http://www.epa.gov/ord/osp/spc> (policy, guidance, and planning and scoping lessons)
- ◆ <http://www.epa.gov/ncea/raf> (health and ecorisk guidelines, framework)
- ◆ <http://www.epa.gov/pesticides/cumulative> (pesticides guidance and results)
- ◆ See also program and regional websites